[ORAL ARGUMENT SCHEDULED FOR APRIL 23, 2019]

No. 18-5312

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN CLINICAL LABORATORY ASSOCIATION,

Plaintiff-Appellant,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,

Defendant-Appellee.

On Appeal from the United States District Court
for the District of Columbia

BRIEF FOR APPELLEE

Of Counsel:

ROBERT P. CHARROW
General Counsel

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

DEBRA M. LABOSCHIN
Attorney

U.S. Department of Health and Human Services

JOSEPH H. HUNT
Assistant Attorney General

ABBY C. WRIGHT
DENNIS FAN
Attorneys, Appellate Staff
Civil Division, Room 7213
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-2494
dennis.fan@usdoj.gov

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), counsel certifies as follows:

A. Parties and Amici

Plaintiff-appellant is the American Clinical Laboratory Association. Defendant-appellee is Secretary Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services. Amici curiae in district court and in this Court are the National Association for the Support of Long Term Care, the Advanced Medical Technology Association, the American Association of Bioanalysts, and the College of American Pathologists.

B. Rulings Under Review

The rulings under review (issued by Judge Amy Berman Jackson) are the memorandum opinion and order filed on September 21, 2018. JA434, 435. The memorandum opinion is reported at *American Clinical Laboratory Association v. Azar*, 334 F. Supp. 3d 301 (D.D.C. 2018).

C. Related Cases

This case has not previously been before this Court or any other court, and counsel is unaware of any related cases.

s/ Dennis Fan
DENNIS FAN

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GLOSSARY

ACLA	American Clinical Laboratory Association
GAO	Government Accountability Office
HHS	United States Department of Health and Human Services
OIG	Office of Inspector General, United States Department of Health and Human Services
PAMA	Protecting Access to Medicare Act of 2014

STATEMENT OF JURISDICTION

Plaintiff's complaint invokes the district court's jurisdiction under 28 U.S.C. § 1331. JA13. The court entered an order dismissing the case for lack of subject-matter jurisdiction on September 21, 2018. JA434. Plaintiff filed a timely notice of appeal on October 19, 2018. JA448. This Court has jurisdiction over this appeal under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Congress enacted Section 216 the Protecting Access to Medicare Act of 2014 ("PAMA") to revise how the Medicare program pays for clinical diagnostic laboratory tests. PAMA directs the Secretary of Health and Human Services to set Medicare payment rates based on the amount that private payors—*e.g.*, insurance companies—have paid for the same test. To establish the new rates, the Secretary promulgated a rule specifying which laboratories must report private-sector payment data, what data should be reported, and when reporting should occur. The issue presented is:

Whether the district court properly concluded that PAMA, 42 U.S.C. § 1395m-1(h)(1), which precludes "judicial review . . . of the establishment of payment amounts," bars plaintiff's suit to enjoin the new PAMA payment rates.

PERTINENT STATUTES AND REGULATIONS

This brief's addendum reproduces pertinent statutes and regulations.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

The federal Medicare program provides health insurance to individuals who are elderly or disabled. *See* 42 U.S.C. § 1395 *et seq.* Through Part A of Medicare, the United States Department of Health and Human Services ("HHS") reimburses healthcare providers for delivering inpatient care, including hospital stays or hospice services. *Id.* § 1395c *et seq.* Part B of Medicare covers outpatient care, including hospital outpatient services and doctor's visits. *Id.* § 1395j *et seq.* This action involves Medicare payments for diagnostic tests conducted by clinical laboratories—laboratories that test, for example, blood or urine samples.

A. History Of The Clinical Laboratory Fee Schedule

Historically, Medicare paid for laboratory tests in one of two ways. *See* Deficit Reduction Act of 1984, Pub. L. No. 98-369, 98 Stat 494. First, when those laboratory tests took place in connection with inpatient or outpatient *hospital* care, Medicare Part A and Part B generally reimbursed the hospital a single amount for a bundle of related services. *See* 42 U.S.C.

§§ 1395*l*(t) (outpatient), 1395ww(d) (inpatient). That bundled payment did not identify how much was being paid for any particular service provided or test conducted. JA16.

Second, when laboratory tests took place *outside* of the inpatient and outpatient hospital setting—for instance, at a doctor's office or at an independent laboratory—the reimbursement process differed. Medicare paid those laboratories directly, primarily under a fee schedule that specified the payment rate for each test. *See* 42 U.S.C. § 1395*l*(h)(1)(B). Payment rates under this Medicare clinical laboratory fee schedule were based on the lesser of a local fee schedule, a national limitation amount, and the amount the laboratory actually billed. *Id.* § 1395*l*(a)(1)(D), (2)(D). The 57 different local fee schedules reflected the "prevailing charge[s]" in varying localities, *id.* § 1395*l*(h)(2)(A)(i), while the national limit reflected a percentage of the median of all the local fee schedules, *id.* § 1395*l*(h)(4)(B). Congress regularly made adjustments to those local schedules, *see id.* § 1395*l*(h)(2)(A)(ii)-(v), and the national limit, *see id.* § 1395*l*(h)(4)(B)(i)-(viii).

In 2013, the Office of Inspector General ("OIG") of HHS released a study of Medicare's laboratory reimbursements. *See* OIG, HHS, OEI-07-11-00010, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial*

Savings (June 2013), https://go.usa.gov/xE3PW ("2013 OIG Report"). That report compared "Medicare payment rates for clinical lab services with payment rates for other health care service payers" and found that "Medicare paid between 18 and 30 percent more" than private insurance companies for a range of laboratory tests. *Id.* at 1, 13. On those tests, Medicare could have saved $910 million yearly—over 38% of Medicare's spending—by reimbursing at the lowest private-sector rate. *Id.* at 13. The report recommended seeking legislation "to set accurate and reasonable payment rates for lab tests" and to s"obtain market rates." *Id.*; *see* JA453.

B. Protecting Access to Medicare Act of 2014

In April 2014, Congress enacted Section 216 of the Protecting Access to Medicare Act of 2014, replacing the prior payment system for clinical diagnostic laboratory tests with a market-based approach for reimbursing those tests. *See* PAMA, Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053-61 (codified at 42 U.S.C. § 1395m-1). PAMA directs the Secretary to establish Medicare payment rates by approximating what a private payor—*e.g.*, an insurance company—would pay a laboratory for that same test.

1. Congress prescribed a process for establishing Medicare payment rates. Congress first required the "[r]eporting of private sector payment

rates for establishment of [M]edicare payment rates." 42 U.S.C. § 1395m-1(a). PAMA provides that, for most tests, each "applicable laboratory . . . shall report to the Secretary" data on private-sector payment amounts every three years, beginning in 2016. *Id.* § 1395m-1(a)(1). Specifically, each "applicable laboratory" must internally collect payment data over a specified time period, *id.* § 1395m-1(a)(4), and then report to the Secretary "[t]he payment rate . . . that was paid by each private payor for the test during the period" and "[t]he volume of such tests for each such payor for the period," *id.* § 1395m-1(a)(3)(A).

PAMA identifies the "applicable laboratory" that must take these steps. "The term 'applicable laboratory' means a laboratory that, with respect to its revenues under [Medicare], a majority of such revenues are from" three sources of Medicare laboratory reimbursements: (1) the new PAMA payment system (once in effect); (2) the old clinical laboratory fee schedule; or (3) a separate fee schedule that covers physician payments. 42 U.S.C. § 1395m-1(a)(2) (referencing "this section, section 1395*l*(h) of this title, or section 1395w-4 of this title"). In other words, PAMA provides that only laboratories where a majority of Medicare revenues come from direct Medicare laboratory reimbursements—and not inpatient or outpatient

payments to hospitals for bundled laboratory services—are "applicable" laboratories that must report data. The statute also authorizes the Secretary to "establish a low volume or low expenditure threshold" to exempt smaller laboratories from the definition of "applicable laboratory." *Id.* Congress also generally authorized the Secretary to "establish through notice and comment rulemaking parameters for data collection." *Id.* § 1395m-1(a)(12).

PAMA then directs the Secretary to set payment rates for each test at the "weighted median" of the reported private-sector payment amounts. 42 U.S.C. § 1395m-1(b)(1)(A). A "weighted median" is simply the middle amount that private payors have paid for a particular test at applicable laboratories, after counting the total number of payments for that test. Take this example: if Laboratory A conducts 2 tests at $100 each and Laboratory B conducts 1 test at $300 each, then $100 is the weighted median for that test because it is the middle amount of $100, $100, and $300. *Id.* § 1395m-1(b)(2). Once calculated, such PAMA payment rates apply to all laboratories—not only applicable laboratories—for three years until the rates are updated following the next data-reporting period. *Id.* § 1395m-1(b)(4)(A). During those three years, the rates "shall not be subject

to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)." *Id.* § 1395m-1(b)(4)(B).

Realizing that Medicare payment rates would likely decrease following the enactment of PAMA, *see* 2013 OIG Report, Congress created a "[p]hase-in of reductions from [the] private payor rate implementation" by setting a limit on how much rates for laboratory tests could decrease annually during each of the first six years. 42 U.S.C. § 1395m-1(b)(3) (10% each year for 2017 to 2019, 20% each year for 2020 to 2022).

2. In enacting PAMA, Congress also set forth the availability of administrative and judicial review. As particularly relevant here, section 1395m-1(h)(1) precludes review of the Secretary's "[i]mplementation" of PAMA by providing that "[t]here shall be no administrative review or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of the establishment of payment amounts under this section." 42 U.S.C. § 1395m-1(h)(1); *see id.* §§ 1395ff (Departmental Appeals Board), 1395oo (Provider Reimbursement Review Board).

At the same time, PAMA retains the ordinary "appeals and review process" for coverage determinations, 42 U.S.C. § 1395m-1(g)(1)(A), regarding "whether or not a particular item or service" can be reimbursed

by Medicare, *id.* § 1395ff(f)(2)(B); *see id.* § 1395m-1(g)(1)(B) (citing "process" under 42 U.S.C. § 1395ff(f)(1)(B) for national determinations). In addition, although PAMA authorizes the Secretary to impose civil money penalties for failing to report or misrepresenting data, *see id.* § 1395m-1(a)(9) (incorporating 42 U.S.C. § 1320a-7a(c)-(s)), aggrieved persons may "obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the [Secretary's] claim or specified claim was presented," *id.* § 1320a-7a(e).

PAMA also includes independent oversight mechanisms. First, Congress directed the Government Accountability Office ("GAO") to study the "new payment rate[s] for laboratory tests" and whether they "accurately reflect market prices," PAMA § 216(c)(1)(A), 128 Stat. at 1061, and then to report to Congress any "recommendations for . . . legislation and administrative action," *id.* § 216(c)(1)(B), 128 Stat. at 1061; *see* GAO, GAO-19-67, *Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments* (Nov. 2018), https://go.usa.gov/xE3QF ("2018 GAO Report"). Second, Congress authorized the HHS Office of Inspector General to "publicly release" an annual data analysis and to study "the implementation and effect of the new payment system for

laboratory tests." PAMA, § 216(c)(2), 128 Stat. at 1061; *see* OIG, HHS, OEI-09-17-00050, *Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies To Ensure Data Quality* (July 2018), https://go.usa.gov/xE3Um ("2018 OIG Reports"). Third, Congress established "an expert outside advisory panel" to provide input on "the establishment of payment rates" for new tests and offer recommendations to HHS. 42 U.S.C. § 1395m-1(f)(1); *see* Centers for Medicare & Medicaid Services, HHS *Advisory Panel on Clinical Diagnostic Laboratory Tests* (July 3, 2018), https://go.usa.gov/xE3Q6. Fourth, Congress directed the continuation of annual meetings of the Centers for Medicare & Medicaid Services—a component of HHS—"for purposes of receiving comments and recommendations (and data on which the recommendations are based) as described in such section on the establishment of payment amounts." 42 U.S.C. § 1395m-1(f)(3) (incorporating 42 U.S.C. § 1395*l*(h)(8)(B)(iii)); *see* Centers for Medicare & Medicaid Services, HHS, *Annual Laboratory Public Meetings* (Jan. 18, 2019), https://go.usa.gov/xE3Uz.

C. 2016 PAMA Rulemaking

1. In October 2015, the Secretary initiated a rulemaking to implement the new PAMA payment system for clinical diagnostic laboratory tests.

JA517 (80 Fed. Reg. 59,386 (Oct. 1, 2015)). Among other topics, the proposed rule addressed the definition of the "applicable laboratory" that is required to collect and report data.

Based on PAMA's instruction that an "applicable" laboratory is one where "a majority of [Medicare] revenues" come only from Medicare laboratory reimbursements (either under the new PAMA system, the old clinical laboratory fee schedule, or the physician fee schedule), the Secretary proposed a method for identifying a laboratory's *total* Medicare revenues. 42 U.S.C. § 1395m-1(a)(2). The proposed rule would have identified each laboratory's total Medicare revenues at the corporate level, based on the entity's taxpayer-identification number—the number used to report revenues to the Internal Revenue Service and "to identify the entity of record that is authorized to receive Medicare payments." JA524. That proposal would generally exempt hospital laboratories from the definition—which use the hospital's tax number—because hospitals principally obtain Medicare revenue from bundled inpatient and outpatient hospital payments, and not from Medicare laboratory reimbursements. JA525 (referencing 42 U.S.C. §§ 1395*l*(t), 1395ww(d)).

The Secretary, however, requested comments regarding whether to identify laboratories' total Medicare revenues based instead on each entity's National Provider Identifier. The National Provider Identifier is a unique identifier that any healthcare provider may obtain and that is used to enroll in Medicare. JA524. A hospital with a tax number, for example, might house a number of smaller components or laboratories, each with their own National Provider Identifiers. *Id.*

2. Following over 1,300 public comments—including comments from plaintiff American Clinical Laboratory Association ("ACLA")—the Secretary adopted a final rule implementing PAMA in June 2016. JA451 (81 Fed. Reg. 41,036 (June 23, 2016)); *see* 42 C.F.R. § 414.500 *et seq.* The Secretary first defined the term "laboratory" consistent with the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a(a), as that term is not defined in PAMA or the Medicare statute. *See* 42 C.F.R. § 414.502, *Applicable laboratory* (1) (2017).

The Secretary then decided to identify laboratories' total Medicare revenues based on the entity's National Provider Identifier—and not its corporate tax number—in an effort to include certain hospital laboratories as "applicable" laboratories. *See* 42 C.F.R. § 414.502, *Applicable laboratory* (2)

(2017). The Secretary explained that a subset of laboratories that are components of hospitals may nonetheless provide outreach services to the public, "furnish[ing] laboratory tests for patients [who] are not admitted hospital inpatients or registered outpatients of the hospital." JA460. These hospital outreach laboratories may therefore be "distinguishable from hospital laboratories in that they are enrolled in Medicare separately from the hospital." *Id.* Based on this distinction, a number of commenters suggested that hospital outreach laboratories "compete with independent laboratories and therefore must be able to report private payor rates." *Id.*

The Secretary explained that his adopted approach would require any hospital outreach laboratory with a National Provider Identifier separate from that of the hospital to report data if those laboratories also obtained a majority of total Medicare revenues not from bundled hospital payments but from Medicare laboratory reimbursements, as required by PAMA. *See* 42 U.S.C. § 1395m-1(a)(2). The Secretary therefore stressed that "[h]ospital outreach laboratories will be able to be included as applicable laboratories." JA461. The Secretary recognized that "[h]ospital laboratories that are not outreach laboratories, on the other hand, would be unlikely to get their own [National Provider Identifier] and bill Medicare

for laboratory services because the laboratory services they furnish are typically primarily paid for as part of bundled payments made to the hospital." *Id.*

The Secretary also explained his decision to reject proposals to identify total Medicare revenues based solely on laboratory certificates, under which each laboratory is authorized to operate pursuant to the Clinical Laboratory Improvement Amendments. The Secretary explained that "unlike for example, the [National Provider Identifier], with which revenues for specific services can easily be identified, the [laboratory] certificate cannot be used to identify revenues for specific services." JA461. The Secretary further rejected plaintiff's comment that HHS could nonetheless devise a formula to approximate what portion of the bundled Medicare payments to hospitals were attributable to the laboratory components of those hospitals. *Id.* Plaintiff indeed recognized that, even "under this approach, many hospitals would not qualify as applicable laboratories." JA623.

The Secretary additionally set a low-expenditure threshold for laboratories in its definition, "minimizing the reporting burden for laboratories that receive a relatively small amount of revenues" from

Medicare laboratory reimbursements. JA465-66; *see* 42 C.F.R. § 414.502, *Applicable laboratory* (4) (2017) (setting $12,500 threshold). This threshold would exempt "approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories." JA466. But because a small number of laboratories perform the bulk of testing in the United States, Medicare would still "retain[] a high percentage" of data on Medicare spending—over 90% from each of those laboratory types—and the threshold therefore would "not materially affect the quality and sufficiency of the data we needed to set rates." *Id.* (roughly 92% of spending from physician's offices and 99% of spending from independent laboratories).

3. In 2017, following promulgation of the final rule, HHS "received applicable information from laboratories in every state, the District of Columbia, and Puerto Rico," including "private payor rates for almost 248 million laboratory tests conducted by 1,942 applicable laboratories." 83 Fed. Reg. 35,704, 35,859 (July 27, 2018). The Secretary observed that "the largest laboratories dominate the market, and therefore, most significantly affect the payment weights," and that the reporting "was sufficient and resulted in accurate weighted medians of private payor rates." *Id.* The

new PAMA payment rates have gone into effect for tests conducted between 2018 and 2020. *See* 2018 OIG Report, app. B.

D. 2018 PAMA Rulemaking

In July 2018, following this suit, HHS revisited in a proposed rule these PAMA policies for the next data-collection and data-reporting periods (which would apply to payment rates for tests conducted between 2021 to 2023). *See* 83 Fed. Reg. 35,704; 2018 OIG Report, app. B. Several months later, the Secretary in a final rule addressed the concern that some hospital outreach laboratories did not have a National Provider Identifier separate from that of the hospital. 83 Fed. Reg. 59,542, 59,571-77 (Nov. 23, 2018). Specifically, the Secretary amended the definition of "applicable laboratory" to include an additional provision that could require more hospital outreach laboratories to report data, by providing that they would use a particular Medicare billing form to determine their total Medicare revenues. *Id.* at 59,575; *see* 42 C.F.R. § 414.502, *Applicable laboratory* (2)(i) (2019).[2]

[2] That billing form is known as a "Form CMS-1450 14x Type of Bill," which is used to bill Medicare for non-patient services by hospital outreach laboratories.

II. PRIOR PROCEEDINGS

Plaintiff is a nonprofit organization that represents a number of laboratories. JA14. In December 2017, plaintiff brought this action under the Administrative Procedure Act ("APA") to challenge HHS's rules for collecting and reporting the data that are used "to establish new market-based Medicare payment rates." JA18. Plaintiff claimed that the 2016 rule's definition of "applicable laboratory" using a National Provider Identifier was too narrow and otherwise unlawful. JA32-37. Plaintiff requested that the district court direct the Secretary "to withdraw or suspend [the 2016] final rule" and "withhold applying the new [payment rates] until such time as the Secretary has made appropriate revisions to [that] final rule." JA39. Plaintiff further sought an injunction requiring HHS "to maintain current laboratory payment rates." JA38.

In September 2018, the district court concluded that it lacked subject-matter jurisdiction and dismissed the suit. JA434. The court's opinion explained that the plain text of section 1395m-1(h)(1) precludes judicial review of "the establishment of payment amounts" under PAMA. JA440.

The district court rejected plaintiff's argument that review was available because it challenged only the definition of the "applicable

laboratory" that reports data and not payment rates, reasoning that "it is clear from the statute that the data gathered" from laboratories "is gathered specifically for the purpose of calculating payment rates for clinical diagnostic laboratory tests" under PAMA. JA442. The court observed, too, that PAMA's section headings contemplated that the definition of "applicable laboratory" is in fact a component of the "[r]eporting of private sector payment rates *for establishment of* [*M*]*edicare payment rates*." *Id.* (quoting 42 U.S.C. § 1395m-1(a)). The court thus explained that "the data reported . . . feeds directly into the payment calculation . . . , and it is not being accumulated for any other purpose." JA443. Relying on this Court's decision in *Florida Health Sciences Center, Inc. v. Secretary of HHS*, 830 F.3d 515 (D.C. Cir. 2016), which "provides clear guidance," the court held that this action was barred by section 1395m-1(h)(1). JA443.

The district court next rejected plaintiff's argument that the requirement that HHS undertake notice-and-comment rulemaking to establish the parameters of data collection meant that judicial review was necessarily available. JA445-46. Additionally, because PAMA does not "regulate the work of laboratories," the court was equally unpersuaded by

plaintiff's contention that judicial review was required because the challenged rules regulate the "primary conduct" of private parties. JA446.

SUMMARY OF ARGUMENT

Through PAMA, Congress directed the Secretary of HHS to establish new Medicare payment rates for laboratory tests that would reflect private-sector payment rates. PAMA instructs the Secretary to establish payment amounts by determining which laboratories should collect and report data, when they should report data, what data should be reported, and the weighted median of the reported data. Section 1395m-1(h)(1) then provides that "[t]here shall be no administrative or judicial review . . . of the establishment of payment amounts under this section." 42 U.S.C. § 1395m-1(h)(1).

The district court correctly concluded that it lacked subject-matter jurisdiction to review plaintiff's challenge. The ordinary meaning of "the establishment of payment amounts" includes the steps taken to reach the ultimate payment amounts, steps that plainly include defining which laboratories must report private-payor amounts. 42 U.S.C. § 1395m-1(h)(1). The structure of PAMA reinforces this reading, setting forth that the definition of "applicable laboratory" is but one component of the broader

implementation of the statute. However framed, plaintiff's action to enjoin the Secretary from "applying the new [payment rates]" and "to maintain current laboratory payment rates" is covered by the plain terms of section 1395m-1(h)(1), and this suit is therefore barred. JA38-39.

Plaintiff therefore cannot escape this conclusion by recasting this action as a challenge to the Secretary's definition of "applicable laboratory" in the 2016 rule. Relying on *Florida Health Sciences Center, Inc. v. Secretary of HHS*, 830 F.3d 515, 519 (D.C. Cir. 2016), the district court additionally explained that review is unavailable where the challenged agency action is inextricably intertwined with unreviewable agency action. JA445. As the district court recognized, "the data reported" by "applicable laboratories" "feeds directly into the payment calculation . . . , and it is not being accumulated for any other purpose." JA443. Thus, even assuming defining "applicable laborator[ies]" is not encompassed within "establish[ing] payment amounts," it is without a doubt inextricably intertwined with the ultimate payment rates.

Plaintiff nonetheless posits that section 1395m-1(h)(1) applies only to the Secretary's ultimate calculation, not to the challenged 2016 rule. But this interpretation cannot be squared with the statutory text or common

sense. Plaintiff's interpretation would implausibly mean that Congress precluded review of only the Secretary's basic median computation, but provided review for all determinations leading to the computation. A materially identical argument was considered and rejected in *Florida Health*. Unable to offer a plausible reading of the statute, plaintiff offers only abstract distinctions focused on "notice-and-comment rulemaking" (versus other rulemaking) or "primary conduct" (versus secondary conduct) that have no basis in the text of section 1395m-1(h)(1). Ultimately, plaintiff's distinctions cannot be squared with the clear statutory text, this Court's precedents, or the broader purposes of PAMA to ensure the stability of the new payments rates and to provide only tailored oversight mechanisms.

Last, plaintiff cannot obtain review by repackaging this action as a challenge to *ultra vires* agency action. The Secretary exercised his statutory authority to "establish through notice and comment rulemaking parameters for data collection" when defining "applicable laboratory." 42 U.S.C. § 1395m-1(a)(12). The term "laboratory" lacks a statutory definition, and the Secretary required an "applicable" laboratory to identify total Medicare revenues based on its National Provider Identifier, which enables such a laboratory to determine whether "a majority of [Medicare]

revenues" comes from one of the three sources of Medicare laboratory reimbursements specified in PAMA and whether reporting is thus required. *Id.* § 1395m-1(a)(2). Plaintiff's mere contention that the rule is underinclusive of hardly means that the Secretary acted "beyond the *scope* of [his] lawful authority," *Florida Health*, 830 F.3d at 522 (emphasis added), and simply underscores that this is a "[g]arden-variety" arbitrary-and-capricious challenge of the sort barred by the statute. *Griffith v. FLRA*, 842 F.2d 487, 493 (D.C. Cir. 1988).

This Court should affirm.

STANDARD OF REVIEW

This Court reviews the district court's dismissal for lack of subject-matter jurisdiction de novo. *Paralyzed Veterans of Am. v. United States Dep't of Transp.*, 909 F.3d 438, 443 (D.C. Cir. 2018).

ARGUMENT

THE TEXT, STRUCTURE, AND PURPOSE OF PAMA EACH CONFIRM THAT THE STATUTE PRECLUDES JUDICIAL REVIEW OF PLAINTIFF'S CHALLENGE TO THE PAMA PAYMENT RATES

A. The District Court Correctly Concluded That Section 1395m-1(h)(1) And This Court's Precedents Bar This Suit

The district court properly concluded that Congress has precluded judicial review of plaintiff's suit. This Court considers a statute's "express

language" to determine "[w]hether and to what extent a particular statute precludes judicial review," and also examines whether the "presumption favoring judicial review of administrative action . . . may be overcome by inferences of intent drawn from the statutory scheme as a whole." *Sackett v. EPA*, 566 U.S. 120, 128 (2012) (quoting *Block v. Community Nutrition Inst.*, 467 U.S. 340, 345, 349 (1984)). Plaintiff seeks to enjoin the new PAMA payment rates (in effect from 2018 to 2020), to require the Secretary to revise those rates, and to reinstate the old Medicare rates in the meantime. JA38-39. The text, structure, and purpose of PAMA and this Court's precedents confirm that this suit is barred.

1. Section 1395m-1(h)(1) broadly provides that "[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of the establishment of payment amounts under this section." 42 U.S.C. § 1395m-1(h)(1). This Court has repeatedly held that "virtually identical language" in other Medicare statutes "unequivocally precludes review of the agency action that falls within the bar." *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 518 (D.C. Cir. 2016) (quotation omitted); *see Texas Alliance for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408-09 (D.C. Cir. 2012) (concluding "presumption of

reviewability here is overcome by [such] specific and emphatic statutory language prohibiting judicial review").[3]

The district court thus correctly held that section 1395m-1(h)(1)'s text bars plaintiff's attempt to challenge the new PAMA payment rates. To begin, the meaning of the phrase "the establishment of payment amounts" is plain. Section 1395m-1(h)(1) naturally encompasses the Secretary's "bring[ing] [payment amounts] about or into existence." *Establish*, Black's Law Dictionary (10th ed. 2014). Establishing Medicare payment amounts based on what private payors spend on laboratory tests naturally involves identifying which laboratories must report data, specifying what private-sector data is required, setting the timeframe for when reporting should occur, and finally calculating the payment rate from that data. The statute bars judicial review of all components of the "establishment of payment rates," including identifying which laboratories must report data.

[3] Other courts of appeals have concluded the same with regard to other Medicare provisions. *See, e.g.*, *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 (5th Cir. 2012); *American Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 452 (7th Cir. 2002); *Painter v. Shalala*, 97 F.3d 1351, 1355-56 (10th Cir. 1996).

Section 1395m-1(h)(1)'s reference to "the establishment of payment amounts *under this section*" confirms that reading. 42 U.S.C. § 1395m-1(h)(1) (emphasis added). The relevant *section* articulates the step-by-step process for establishing payment rates, and review of any of those steps is thus precluded. *See Knapp Medical Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) (holding that preclusion statute's use of "'under this paragraph'" covers actions taken under any subparagraph of "the entire" paragraph). Subsection (a) provides for the "[r]eporting of private sector payment rates for *establishment of* [M]edicare payment rates," 42 U.S.C. § 1395m-1(a) (emphasis added), and then walks through what constitutes an "applicable laboratory" (subsection (a)(2)), how those laboratories must collect and report data (subsection (a)(3) and (4)), and how to ensure accurate and complete reporting (subsection (a)(5) to (7)). Congress authorized the Secretary to implement these "parameters for data collection," as the Secretary did here in his 2016 rule. *Id.* § 1395m-1(a)(12). Then, subsection (b) addresses how to use "private payor rate information to determine

[M]edicare payment rates," *id.* § 1395m-1(b)(1), by calculating the weighted median of the reported data, *id.* § 1395m-1(b)(2).[4]

Indeed, plaintiff's own complaint confirms that determining which laboratories must report data is part of establishing payment amounts. Although plaintiff purports to challenge only the definition of "applicable laboratory," the relief plaintiff seeks is to require HHS "to maintain current laboratory payment rates" and to enjoin HHS from "applying the new [payment rates]" under PAMA. JA38-39. In short, plaintiff seeks higher payment amounts through an attack on the Secretary's definition of "applicable laboratory." However framed, that challenge to the payment amounts is barred by the plain text of the statute.

Moreover, a challenge to the PAMA payment amounts is the only basis upon which plaintiff could have standing to bring this suit. Although plaintiff asserts (Br. 33-34) that "standing is self-evident," claiming its members are injured because PAMA requires them to report data, this theory is incompatible with plaintiff's claim that the Secretary incorrectly

[4] Subsections (c) through (e) of section 1395m-1 specify an additional process to establish payments rates for new laboratory tests, but those rates are not challenged here.

exempted too many hospital laboratories from reporting obligations and that *more* of plaintiff's members should report data. *Increasing* reporting obligations could not redress that asserted harm. Plaintiff thus can only rest (Br. 35-36) on the "harm from," in its views, "invalid payment amounts" established by the Secretary.[5] And that suit, as explained, is barred.

2.` Even assuming that the definition of "applicable laboratory" were not encompassed within the plain meaning of "establishment of payment amounts," plaintiff's suit would still be barred under this Court's precedents, as the district court recognized. JA445. This Court's decision in *Florida Health* addressed a Medicare provision precluding review of "[a]ny estimate of the Secretary" for determining Medicare payments to

[5] Because "congressional preclusion of judicial review is in effect jurisdictional, [this Court] need not address . . . standing issues." *Block*, 467 U.S. at 353 n.4 (citing *National R.R. Passenger Corp. v. National Ass'n of R.R Passengers*, 414 U.S. 453, 456 (1974)). The district court did not reach the question whether plaintiff has in fact suffered an injury from lower payments rates or whether the 2016 rule's definition caused that injury. Whether plaintiff can demonstrate that the Secretary caused any injury is uncertain, as the Government Accountability Office has determined that even "collecting ten times as much data from hospital outreach laboratories would increase expenditures by 1 percent" only, and plaintiff has not alleged a preferred methodology that would increase payments by even that minimal amount. 2018 GAO Report 19.

hospitals. 830 F.3d at 518 (quoting 42 U.S.C. § 1395ww(r)(3)). This Court rejected assertions that it could "review the underlying data on which the Secretary relied, because an 'estimate' is not the same thing as the 'data' on which it is based" and because "[t]he estimate is an output, and the data are an input." *Id.* at 519. This Court recognized instead that, based on the statutory bar, courts may not review any predicate agency "decision that was 'indispensable' or 'integral' to, or 'inextricably intertwined' with, the unreviewable agency action." *Id.*

This Court's recent application of the "inextricably intertwined" framework in *Mercy Hospital, Inc. v. Azar*, 891 F.3d 1062 (D.C. Cir. 2018), is equally instructive. There, the Court concluded that a Medicare statute precluding review of the "establishment of . . . prospective payment rates" "must also include the adjustments used to calculate that rate," *id.* at 1066, and judicial review was therefore precluded "[a]s both a textual and a practical matter." *Id.* at 1067. This was because (as here) the "language of the statute ties together" the ultimate payment rate with the earlier adjustments and because (as here), "realistically, a court cannot review any of those adjustments without also reviewing the [payment] rate," as a flawed adjustment necessarily meant an incorrect rate. *Id.* This Court

cautioned that a would-be challengers could not—as plaintiff attempts here—simply design "a pleading so that it circumvents a statutory bar to review." *Id.*

This Court's precedents are determinative here. As was the case in *Mercy Hospital* and *Florida Health*, plaintiff's requested relief would require this Court necessarily to "review[] the [payment] rate[s]" or the "estimate" of private-sector rates and whether those rates correct. *Mercy Hosp.*, 891 F.3d at 1067. Even if the Secretary's definition of "applicable laboratory" were not plainly encompassed within "the establishment of payment amounts" as a textual matter, identifying which laboratories must report private-sector data is "indispensable" and "integral" to approximating private-sector rates. *Florida Health*, 830 F.3d at 519. As the district court observed, the "data reported" by applicable laboratories "feeds directly into the payment calculation . . . , and it is not being accumulated for any other purpose." JA443. In other words, the question whether a definition that leads directly to the payment rates is correct cannot be divorced from the question whether the payment rates themselves are correct.

3. The statutory purpose of PAMA's judicial-review bar underscores the correctness of the government's view. The plain purpose of the

preclusion provision is to permit HHS to "proceed with these initial [PAMA] administrative processes without risk of litigation blocking the execution of the program." *Texas Alliance*, 681 F.3d at 409. Section 1395m-1(h)(1) therefore "protects Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates" and avoids "disruption to the Secretary's administration of the already-complex Medicare program." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232-33 (D.C. Cir. 1994) (addressing Secretary's policy of making only prospective corrections and not "retroactive correction[s]").

Concerns regarding certainty and stability are especially acute here because Congress tasked the Secretary with constructing a new payment system to replace the decades-old payment system for clinical diagnostic laboratory tests within a relatively short timeframe. *See* 42 U.S.C. § 1395*l*(a)(1)(D), (2)(D) (terminating prior schedules by 2017). And Congress's concern with the stability of its new payment system is evident throughout PAMA, which specifies that the new payment rates generally will last for three years uninterrupted, *id.* § 1395m-1(a)(1), (b)(4)(A), and cannot undergo "any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)," *id.*

§ 1395m-1(b)(4)(B). This legislative choice represents a stark departure from Congress's previous frequent modifications of the payment system. *See, e.g.*, *id.* § 1395*l*(h)(2)(A)(ii)-(v), (h)(4)(B)(i)-(viii).

Tellingly, instead of providing for administrative or judicial review of the establishment of payment amounts, Congress provided specific oversight mechanisms in PAMA. *See Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 678 (1986) ("'In the context of the statute's precisely drawn provision' . . . the failure 'to authorize further review'" in some areas "'provides persuasive evidence that Congress deliberately intended to foreclose further review of such claims.'" (quoting *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982))). Specifically, PAMA requires the Government Accountability Office to report to Congress, for legislative branch oversight. PAMA § 216(c)(1), 128 Stat. at 1060-61. PAMA also authorizes the HHS Office of Inspector General to release public data and conduct its own analyses, for independent administrative oversight. *Id.* § 216(c)(2), 128 Stat. at 1061. PAMA further establishes an expert outside advisory panel, for professional-community oversight. 42 U.S.C. § 1395m-1(f)(1). And, finally, PAMA sets forth annual meetings where any person can submit comments and recommendations, for public oversight. *Id.*

§ 1395m-1(f)(3). Beyond these processes, Congress specified when existing processes for reviewing whether particular tests are covered by Medicare would remain in place. *See* 42 U.S.C. § 1395m-1(g)(1)(A), (B).

B. Plaintiff Offers No Sound Basis To Depart From The Text Of Section 1395m-1(h)(1) Or This Court's Precedents

The district court properly rejected plaintiff's various theories for departing from the statute and from this Court's precedents. JA445-46.

1. Plaintiff erroneously contends (Br. 32, 38) that PAMA precludes review of the ultimate calculation of payment rates under subsection (b) of section 1395m-1, but *not* the Secretary's 2016 action of defining "applicable laboratory" (or other agency actions) taken under subsection (a). This reading of the statute is without merit. First, as a textual matter, section 1395m-1(h)(1) does not distinguish between actions taken under subsection (a) or subsection (b), but instead applies to "this section." Subsection (a), moreover, contains statutory provisions that expressly concern the "[r]eporting of private sector payment rates *for establishment of* [M]edicare payment rates," 42 U.S.C. § 1395m-1(a) (emphasis added), confirming that agency actions under subsection (a) are covered by the preclusion provision. *See Merit Mgmt. Grp. v. FTI Consulting, Inc.*, 138 S. Ct. 883, 893

(2018) (observing section heading "[r]einforc[es] that reading of the [statutory] provision").

As we explained (*supra* pp. 21-28), subsection (a) describes an inseparable part of the rate-establishment process, and review of agency actions prescribed by subsection (a) is necessarily also barred. Indeed, had Congress intended solely to shield the ultimate calculation, it would not have used language in section 1395m-1(h)(1) that plainly covers the bringing about of—hence, *the establishment of*—payment amounts. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) ("It is our duty to give effect, if possible, to every clause and word of a statute." (quotation omitted)). Consistent with this understanding, section 1395m-1(h)(1)'s heading thus twice describes the preclusion of judicial review as covering PAMA's entire "[i]mplementation." *See Merit Mgmt.* 138 S. Ct. at 893.

Plaintiff's reading finds as little support in common sense as it finds in the text. Subsection (b) directs the Secretary to perform a single, basic mathematical function for each type of test: HHS takes the private-sector payments reported and selects the weighted median. For example, if Laboratory A conducted a test 2 times at $100 each and Laboratory B conducted a test 1 time at $300 each, then $100 is the "weighted median"

because that is the middle amount of $100, $100, and $300. *See* 42 U.S.C. § 1395m-1(b)(1)(A), (2). Plaintiff frames this as "'arraying the distribution of all [reported] payment rates,'" "applying a formula," and "'calculat[ing] a weighted median.'" Br. 38 (quoting 42 U.S.C. § 1395m-1(b)(1)-(5)); *see* Br. 53 (cautioning against "enmeshing the courts in technical calculations and discretionary decisions about how to array data"). But the calculation of a median is standard math. It is implausible that Congress would single out basic math as unreviewable, while permitting review of every discretionary step that preceded that math. *Cf. Michigan Acad.*, 476 U.S. at 678 (holding, in converse situation, that review of "what [Congress] characterized as 'trivial' claims" suggests review of other claims).

Plaintiff's interpretation, moreover, would reduce two of PAMA's principal oversight mechanisms to reviewing the Secretary's math homework, as the expert outside advisory panel provides "input on . . . the establishment of payment rates under this section" for new tests, 42 U.S.C. § 1395m-1(f)(1)(A), and public meetings are held for HHS to "receiv[e] comments and recommendations" on "the establishment of payment amounts under this section" generally, *id.* § 1395m-1(f)(3). Congress could

not have plausibly tasked those bodies with only reviewing the Secretary's final computation of a median, as plaintiff's reading requires.

Plaintiff next argues (Br. 38-39, 41-43) that Congress would have used language specifically precluding review of the "establish[ment] [of] parameters for data collection under this subsection," 42 U.S.C. § 1395m-1(a)(12), if it had meant for section 1395m-1(h)(1) to bar this challenge to the Secretary's definition of "applicable laboratory." This is mistaken. Parameters for collecting data are but one component of establishing market-based rates under PAMA, and Congress chose the more capacious language of precluding review of "the establishment of payment amounts" under PAMA as a whole. Far from omitting key language from section 1395m-1(h)(1), as plaintiff asserts (Br. 39), Congress used "broader language" to prevent a more "limiting" construction that might have covered only parameters such as the definition of "applicable laboratory." *Orff v. United States*, 545 U.S. 596, 603 (2005). In any event, even if section 1395m-1(h)(1) is given a narrower construction, the parameters for collecting data are by necessity intertwined with the ultimate calculation of payment rates. *See Florida Health*, 830 F.3d at 519; *supra* pp. 26-28.

2. Lacking any textual or logical basis for its interpretation, plaintiff contends (Br. 39-41, 46-51) that judicial review is proper because the 2016 rule was "promulgated through notice-and-comment rulemaking." But section 1395m-1(h)(1) does not distinguish between agency rulemaking and the other administrative actions needed to establish payment amounts, and such "[g]eneralizations as to when judicial review of administrative action may or may not be obtained are of course hazardous." *Switchmen's Union v. National Mediation Bd.*, 320 U.S. 297, 301 (1943); *see, e.g.*, *Florida Health*, 830 F.3d at 517 (precluding challenge to notice-and-comment rulemaking on what data to use). Nor does the preclusion of APA review depend on the difference between rulemaking and other agency actions (*see* Br. 48), as Congress may bar review of *any* agency action (without differentiation) by enacting "statutes [that] preclude judicial review." 5 U.S.C. § 701(a)(1) (providing such statutes are exceptions to "[t]his chapter" as a whole). A judicial-review bar therefore precludes review of any specified "agency action that falls within the bar." *Florida Health*, 830 F.3d at 518

Plaintiff's related assertion (Br. 50-51) that HHS has "regulate[d] primary conduct" also gains no ground. As the district court emphasized, the challenged rule does not "regulate the work of laboratories" because,

with respect to testing, each laboratory is "'free to conduct its business as it sees fit.'" JA446 (quoting *National Park Hosp. Ass'n v. Department of Interior*, 538 U.S. 803, 810 (2003)). And, as we explained (*supra* pp. 25-26), plaintiff does not allege here that the Secretary has required too many of plaintiff's members to report data; rather, plaintiff alleges that the Secretary has erroneously permitted *underreporting*. Moreover, this Court has not endorsed an abstract distinction between primary and secondary conduct in interpreting preclusion statutes, holding for example that review of a regulation requiring private parties to submit financial documentation was also precluded. *See Texas Alliance*, 681 F.3d at 406-08 (precluding review, even with claim that the rule required notice-and-comment rulemaking).

Indeed, plaintiff's myriad cases (Br. 48-51) do not include any where the Supreme Court or this Court has accepted plaintiff's proposed distinction between primary and secondary conduct with respect to the preclusion of judicial review where review would be available absent a statutory bar. Instead, those cases represent distinct situations in which there is a failure to meet even the basic requirements of a sufficiently concrete case or controversy. *See, e.g.*, *Texas v. United States*, 523 U.S. 296, 301 (1998) (ripeness); *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 891 (1990)

(ripeness); *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 164-65 (1967) (ripeness).; *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986) (final agency action).

Last, plaintiff urges (Br. 31, 46, 54-56, 61) that direct review of the Secretary's rule must be available because the Secretary could impose a civil money penalty for misreporting information, raising "serious constitutional concerns" if review were unavailable. But plaintiff misreads the statute. The civil money penalty provision in PAMA, 42 U.S.C. § 1395m-1(a)(9), incorporates the general statutory procedures for reviewing such penalties, *id.* § 1395m-1(a)(9)(B) (incorporating 42 U.S.C. § 1320a-7a(c)-(s)). Those procedures set forth the available administrative proceedings, *id.* § 1320a-7a(d), and provide that aggrieved persons "may obtain a review of [a resulting] determination in the United States Court of Appeals for the circuit in which the person resides, or in which the [Secretary's] claim or specified claim was presented," *id.* § 1320a-7a(e). Notwithstanding plaintiff's vague overtures (Br. 48) to preenforcement review, there have been no "threatened [penalty] proceedings" that "may give rise to harm sufficient to justify pre-enforcement review," *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 165 (2014), as the Secretary has never

attempted to impose PAMA penalties, *see* 2018 OIG Report 14 (providing that Secretary may institute "a plan to issue civil monetary penalties" for "*future* data reporting periods," which would take place under 2018 rule (emphasis added)). Plaintiff's assertion (Br. 28) that "ACLA's members and other laboratories will continue to face civil penalties for noncompliance" is thus inaccurate. And given plaintiff's claim that the 2016 rule *exempts too many* laboratories from the reporting and misreporting requirements, plaintiff's purported fear of civil money penalties is irreconcilable with its own theory of the case.

C. Plaintiff's Attempt To Bring An *Ultra Vires* Claim Fails

This Court should also reject plaintiff's "attempts to repackage its arguments to fall within a line of cases in which [the Court] ha[s] found jurisdiction to review an agency's action that is *ultra vires*." *Florida Health*, 830 F.3d at 522. Even assuming there is "sufficient ambiguity" in the statute "to trigger the presumption that judicial review of allegedly *ultra vires* agency action is favored," such review is unavailable here. *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004); *see Board of Governors of Fed. Reserve Sys. v. MCorp Fin., Inc.*, 502 U.S. 32, 43-44 (1991) (concluding statute provides "clear and convincing evidence" to overcome presumption of

"judicial review of any agency action that is alleged to have exceeded the agency's statutory authority"); JA442-43 (holding preclusion was "clear from the statute" and "clear" from this Court's precedents).

To obtain *ultra vires* review, plaintiff must identify a "patent violation of agency authority," *Florida Health*, 830 F.3d at 522 (quoting *Independent Cosmetic Mfrs. & Distribs., Inc. v. United States Dep't of Health, Educ. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978)), such that review becomes "available to reestablish the limits on [the Secretary's] authority," *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988). Plaintiff has made no showing that providing a regulatory definition of "applicable laboratory" that identifies total Medicare revenues based on National Provider Identifiers exceeds the Secretary's authority or that the agency has engaged in "'shenanigans' by exceeding its statutory bounds." Br. 61 (quoting *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018)).[6]

[6] Even were *ultra vires* review available, the scope of relief would be limited to "reestablish[ing] the limits on [the Secretary's] authority." *Dart*, 848 F.2d at 224. Plaintiff would not be entitled to payments under the old clinical laboratory fee schedule, which Congress has authorized the Secretary to apply only to "tests furnished before January 1, 2017." 42 U.S.C. § 1395*l*(a)(1)(D), (2)(D). Nor would the general availability of review resolve the question whether plaintiff is required to undertake actions to administratively exhaust a claim for payment prior to bringing suit.

In defining "applicable laboratory," the Secretary properly exercised his authority to "establish through notice and comment rulemaking parameters for data collection." 42 U.S.C. § 1395m-1(a)(12). Plaintiff cannot dispute that the Secretary needed to define the term "laboratory," because that term remains statutorily undefined. *See* JA457 (defining "laboratory" consistent with Clinical Laboratory Improvement Amendments). PAMA is also silent on *how* to identify total Medicare revenues to determine whether a laboratory is an "applicable" laboratory, and plaintiff apparently concedes (Br. 69) that the Secretary had authority in 2018 to amend the challenged regulation—substantially in favor of plaintiff's approach—to identify hospital outreach laboratories' revenues based on a Medicare billing form. *See* 42 C.F.R. § 414.502, *Applicable laboratory* (2)(i) (2019). Plaintiff's objection amounts to a contention that the 2016 rule was underinclusive of certain hospital laboratories by using National Provider Identifiers to identify total revenues, but that hardly means that the Secretary acted "beyond the *scope* of [his] lawful authority." *Florida Health*, 830 F.3d at 522 (emphasis added).

Moreover, the Secretary's actions were not unreasonable, let alone *ultra vires*. As the Secretary explained, there are a "wide variety of

laboratories (for example, national chains, physician offices, hospital laboratories, etc.)." JA457. For hospital laboratories in particular, Medicare typically reimburses the hospital with a bundled payment for all hospital services provided without differentiating what revenues are attributable to laboratory tests. JA458. Thus, hospital laboratories' total Medicare revenues are not easily quantifiable. Indeed, during the rulemaking, plaintiff "strongly urge[d]" HHS to adopt a *nonstatutory* formula to estimate hospital laboratories' total Medicare revenues by "determin[ing] the *approximate* percentage of revenues paid to hospital [*sic*] for all inpatient and outpatient laboratory services." JA621, 623 (emphasis added); *see* JA621-22, 645-46 (devising formula and percentage based on consulting firm's estimates).[7] The Secretary instead decided to use National Provider

[7] The two equations that plaintiff supplies (Br. 65) to demonstrate that the Secretary engaged in *ultra vires* actions are also neither complete nor accurate. Plaintiff fails to describe its own "correct" equation in a manner that reflects the various additional approximations otherwise required to quantify the total Medicare revenues for hospital laboratories. *See* JA645-46. Plaintiff's description of the Secretary's "incorrect" equation misconstrues the 2016 rule as identifying the "*Hospital's* Total Medicare Revenues." Rather, the 2016 rule identifies the *laboratory's* total Medicare revenues based on its National Provider Identifier, as even hospital laboratories may "obtain[] a unique [National Provider Identifier] (separate from the hospital)." JA461.

Identifiers "to determine revenues and costs" because, for all laboratories with such an identifier, "revenues for [fee schedule] services can be distinguished from other Medicare revenues." JA461.

Plaintiff insists (Br. 66-67) that Congress intended for hospital outreach laboratories to be included as applicable laboratories. Plaintiff cites (Br. 13-14, 67) congressional floor statements made *after* PAMA was enacted in April 2014, *see* 160 Cong. Rec. S2860 (daily ed. May 8, 2014), but such "[p]ost-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011). In any event, plaintiff refuses to wrestle with the Secretary's statements that "[h]ospital outreach laboratories *will be able to be included* as applicable laboratories." JA461 (emphasis added); *see* JA460 ("[W]e are revising our [proposed] definition of applicable laboratory to account for hospital outreach laboratories.").

Contrary to plaintiff's characterizations, the 2016 rule instead exempts a *subset* of a *subset* of *one type* of laboratory—*i.e.*, those hospital laboratories that have outreach services but that do not also have National Provider Identifiers—which is consistent with PAMA's provisions to require reporting only from *applicable* laboratories (not *all* laboratories that

receive Medicare laboratory reimbursements). This case is thus nothing like those where Congress has authorized an agency to regulate one matter but the agency regulates a different matter altogether. *See* Br. of Amici Curiae The College of Am. Pathologists, *et al.* 27-28 (citing *Southwest Airlines Co. v. TSA*, 554 F.3d 1065 (D.C. Cir. 2009)); Br. of Amicus Curiae Am. Ass'n of Bioanalysts 11-12 (citing same). Any argument that the Secretary's rule was underinclusive in including too few applicable laboratories is not an *ultra vires* argument, but instead plainly a "[g]arden-variety" arbitrary-and-capricious challenge for which review is barred. *Griffith v. FLRA*, 842 F.2d 487, 493 (D.C. Cir. 1988).

Plaintiff also suggests (Br. 66-68) that this Court should draw inferences based on the "consequences" of the 2016 rule: that a large number of laboratories did not report data. Yet PAMA only mandates reporting from laboratories with a particular breakdown of Medicare revenues above a low-expenditure threshold, *see* 42 U.S.C. § 1395m-1(a)(2), and the Secretary set payment rates based on data from over "248 million laboratory tests." 83 Fed. Reg. at 35,859. PAMA's plain terms thus instruct the Secretary to use a *sample* of the laboratory market to approximate

market rates, rather than undertake the burden of gathering data from the "market as a whole," as plaintiff mistakenly insists (Br. 2, 35, 67).

As a final matter, paintiff conflates (Br. 22-23) the effect of a low-expenditure threshold and other circumstances on the total reporting with the effect of the National Provider Identifier. *See, e.g.*, 2018 OIG Report 10 (describing "one-time challenges in complying with a new policy"). The threshold in particular "substantially reduce[d] the number of laboratories qualifying as applicable laboratories (that is, approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories)." JA466. But, as the Secretary has explained, HHS could nonetheless "retain[] a high percentage of Medicare utilization" (over 90% of Medicare spending on each laboratory type), *id.*, and the actual reporting "was sufficient and resulted in accurate weighted medians of private payor rates," 83 Fed. Reg. at 35,859. *See* 2018 GAO Report 20 (even assuming the need "to collect 20 percent more data for [HHS's] collection to be complete, doing so could" increase or reduce Medicare payment rates by only "3 percent"); 2018 OIG Report 9 (stating statistical "modeling demonstrated that increased reporting from more labs would not have had a meaningful

effect on 2018 payment rates"). As with plaintiff's other attempts to obtain review, this one too is without merit.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

ABBY C. WRIGHT

s/ DRAFT
DENNIS FAN
Attorneys, Appellate Staff
Civil Division, Room 7213
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-2494
dennis.fan@usdoj.gov

Of Counsel:
ROBERT P. CHARROW
General Counsel
JANICE L. HOFFMAN
Associate General Counsel
SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation
DEBRA M. LABOSCHIN
Attorney
U.S. Department of Health and Human Services

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8,620 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it was prepared using Microsoft Word 2016 in Book Antiqua 14-point font, a proportionally spaced typeface.

s/ Dennis Fan
DENNIS FAN

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Dennis Fan
DENNIS FAN

ADDENDUM

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Protecting Access to Medicare Act of 2014,
Pub L. No. 113-93, § 216, 129 Stat. 1040

SEC. 216. IMPROVING MEDICARE POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

. . . .

(c) GAO STUDY AND REPORT; MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS. —

(1) GAO STUDY AND REPORT ON IMPLEMENTATION OF NEW PAYMENT RATES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS. —

(A) STUDY. —The Comptroller General of the United States (in this subsection referred to as the "Comptroller General") shall conduct a study on the implementation of section 1834A of the Social Security Act, as added by subsection (a). The study shall include an analysis of —

(i) payment rates paid by private payors for laboratory tests furnished in various settings, including —

(I) how such payment rates compare across settings;

(II) the trend in payment rates over time; and

(III) trends by private payors to move to alternative payment methodologies for laboratory tests;

(ii) the conversion to the new payment rate for laboratory tests under such section;

(iii) the impact of such implementation on beneficiary access under title XVIII of the Social Security Act;

(iv) the impact of the new payment system on laboratories that furnish a low volume of services and laboratories that specialize in a small number of tests;

(v) the number of new Healthcare Common Procedure Coding System (HCPCS) codes issued for laboratory tests;

(vi) the spending trend for laboratory tests under such title;

(vii) whether the information reported by laboratories and the new payment rates for laboratory tests under such section accurately reflect market prices;

(viii) the initial list price for new laboratory tests and the subsequent reported rates for such tests under such section;

(ix) changes in the number of advanced diagnostic laboratory tests and laboratory tests cleared or approved by the Food and Drug Administration for which payment is made under such section; and

(x) healthcare economic information on downstream cost impacts for such tests and decision making based on accepted methodologies.

(B) REPORT.—Not later than October 1, 2018, the Comptroller General shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the study under subparagraph (A), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(2) MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS.—The Inspector General of the Department of Health and Human Services shall—

(A) publicly release an annual analysis of the top 25 laboratory tests by expenditures under title XVIII of the Social Security Act; and

(B) conduct analyses the Inspector General determines appropriate with respect to the implementation and effect of the new payment system for laboratory tests under section 1834A of the Social Security Act, as added by subsection (a).

42 U.S.C. § 1395*l*
§ 1395*l*. Payment of benefits.

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1395k(a)(1) of this title—80 percent of the reasonable charges for the services; except that . . . (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1395m-1 of this title (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,,

. . . .

(2) in the case of services described in section 1395k(a)(2) of this title (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1395rr of this title) . . .

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule determined under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1395cc of this title) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1395m-1 of this title (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1395cc of this title) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

. . . .

(h) Fee schedules for clinical diagnostic laboratory tests; percentage of prevailing charge level; nominal fee for samples; adjustments; recipients of payments; negotiated payment rate

(1)

. . . .

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

. . . .

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1395u(b)(3) of this title for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before April 1, 2014, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1395u(b)(3) of this title performed after March 31, 1988, the Secretary shall reduce

by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

. . . .

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

42 U.S.C. § 1395m-1

§ 1395m-1. Improving policies for clinical diagnostic laboratory tests

(a) Reporting of private sector payment rates for establishment of medicare payment rates

(1) In general

Beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary, applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(2) Definition of applicable laboratory

In this section, the term "applicable laboratory" means a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395*l*(h) of this title, or section 1395w-4 of this title. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) Applicable information defined

(A) In general

In this section, subject to subparagraph (B), the term "applicable information" means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) Exception for certain contractual arrangements

Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) Data collection period defined

In this section, the term "data collection period" means a period of time, such as a previous 12 month period, specified by the Secretary.

(5) Treatment of discounts

The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1395w-3a(c)(3) of this title.

(6) Ensuring complete reporting

In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) Certification

An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) Private payor defined

In this section, the term "private payor" means the following:

(A) A health insurance issuer and a group health plan (as such terms are defined in section 300gg-91 of this title).

(B) A Medicare Advantage plan under part C.

(C) A medicaid managed care organization (as defined in section 1396b(m) of this title).

(9) Civil money penalty

(A) In general

If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

(B) Application

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as they apply to a civil money penalty or proceeding under section1320a-7a(a) of this title.

(10) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except—

(A) as the Secretary determines to be necessary to carry out this section;

(B) to permit the Comptroller General to review the information provided;

(C) to permit the Director of the Congressional Budget Office to review the information provided; and

(D) to permit the Medicare Payment Advisory Commission to review the information provided.

(11) Protection from public disclosure

A payor shall not be identified on information reported under this subsection. The name of an applicable laboratory under this subsection shall be exempt from disclosure under section 552(b)(3) of title 5.

(12) Regulations

Not later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection.

(b) Payment for clinical diagnostic laboratory tests

(1) Use of private payor rate information to determine medicare payment rates

(A) In general

Subject to paragraph (3) and subsections (c) and (d), in the case of a clinical diagnostic laboratory test furnished on or after January 1, 2017, the payment amount under this section shall be equal to the weighted median determined for the test under paragraph (2) for the most recent data collection period.

(B) Application of payment amounts to hospital laboratories

The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment under section 1395*l*(t) of this title.

(2) Calculation of weighted median

For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall

calculate a weighted median for the test for the period, by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory.

(3) Phase-in of reductions from private payor rate implementation

(A) In general

Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2022 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than the applicable percent (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year.

(B) Applicable percent defined

In this paragraph, the term "applicable percent" means—

(i) for each of 2017 through 2019, 10 percent; and

(ii) for each of 2020 through 2022, 15 percent.

(C) No application to new tests

This paragraph shall not apply to payment amounts determined under this section for either of the following.

(i) A new test under subsection (c).

(ii) A new advanced diagnostic test[1] (as defined in subsection (d)(5)) under subsection (d).

(4) Application of market rates

(A) In general

Subject to paragraph (3), once established for a year following a data collection period, the payment amounts under this subsection shall

continue to apply until the year following the next data collection period.

(B) Other adjustments not applicable

The payment amounts under this section shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

. . . .

(f) Input from clinicians and technical experts

(1) In general

The Secretary shall consult with an expert outside advisory panel, established by the Secretary not later than July 1, 2015, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests, to provide—

(A) input on—

(i) the establishment of payment rates under this section for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and

(ii) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and

(B) recommendations to the Secretary under this section.

(2) Compliance with FACA

The panel shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(3) Continuation of annual meeting

The Secretary shall continue to convene the annual meeting described in section 1395*l*(h)(8)(B)(iii) of this title after the implementation of this section for purposes of receiving comments and recommendations (and data on which the recommendations are based) as described in such section on the establishment of payment amounts under this section.

(g) Coverage

(1) Issuance of coverage policies

(A) In general

A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1395ff(f)(2)(B) of this title), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).

(B) No effect on national coverage determination process

This paragraph shall not apply to the national coverage determination process (as defined in section 1395ff(f)(1)(B) of this title).

(C) Effective date

This paragraph shall apply to coverage policies issued on or after January 1, 2015.

(2) Designation of one or more medicare administrative contractors for clinical diagnostic laboratory tests

The Secretary may designate one or more (not to exceed 4) medicare administrative contractors to either establish coverage policies or

establish coverage policies and process claims for payment for clinical diagnostic laboratory tests, as determined appropriate by the Secretary.

. . . .

(h) Implementation

(1) Implementation

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of the establishment of payment amounts under this section.

. . . .

42 C.F.R. § 414.502 (2017)

For purposes of this subpart—

. . . .

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

. . . .

42 C.F.R. § 414.502 (2019)

For purposes of this subpart—

. . . .

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(i) For hospital outreach laboratories—bills Medicare Part B on the CMS 1450 under bill type 14x;

(ii) [Reserved]

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

. . . .